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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,055

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Michel Luc Bouchoucha

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EXAMINER

CWERN, JONATHAN

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05/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,055	Applicant(s) BOUCHOUCHA, MICHEL LUC	
	Examiner Jonathan G. Cwern	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/21/08 has been entered.

Claim Objections

Claims 1-4 and 6-20 are objected to because of the following informalities:

Claims 1-3, 6, 9, 12-13, 16-18, and 20 contain improper means plus function language. Claim 11 has no further structural limitation. In claim 14, in the phrase "said at least the three receivers", remove the word "the". In claim 16, the word "analog" is misspelled.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 6-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant's use of the terms reference position and reference phase are confusing. For example, in paragraph [0042], applicant states that the transmitting element is placed in the mouth of the subject and a reference phase is determined. However, later in the paragraph, applicant states that the software will determine the phase shift relative to the reference position. It is therefore unclear how the system operates to determine the position of the device.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 6-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 and 9, it is unclear how the step of "measuring a reference position when said transmitting element is in the mouth of the subject" relates in any way to the rest of the claim. In claim 11, the term "high transmission frequency" is vague.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 9-10, 14, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US 2004/0015075).

Frisch et al. show a method of non-invasive exploration for assessing the digestive motility and/or transit of a human or animal subject, comprising: said subject swallowing an ingestible transmitting element which is non-digestible containing means transmitting at a given fixed frequency (source 100, column 3, line 60 through column 4 line 5); measuring, at a given time using at least three reception means (antenna elements 10a through 10z, column 3, lines 10-22) distributed around said subject's trunk (belt is worn around the body, column 3, lines 13-16); determining by triangulation (column 4, lines 35-40) the position of said element (column 4, lines 10-34); defining, according to the position of said element, a data for the assessment of the digestive motility and/or transit (sensors 110 provide the data, column 3, lines 65-67). Also, the measurements corresponding to the phase shift are stored in memory means (data storage unit 22, column 3, lines 41-42); the receiving means are placed around the abdominal belt (antenna array belt 10, column 3, lines 10-22); a series of position

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measurements are made which are spread over time (beacon may send out an intermittent signal or transmit at the same time as the data signal, column 3 line 67 through column 4, line 9); a non-invasive exploration system for assessing the digestive motility and/or transit of a human or animal subject, in particular for the implementation of the method according to claim 1, characterized by: on the one hand: an ingestible transmitting element which cannot be digested by said subject containing means transmitting at a given fixed frequency (source 100, column 3, line 60 through column 4 line 5); and on the other hand: receiving means comprising at least three receivers (antenna elements 10a through 10z, column 3 lines 10-22) intended to be placed around the trunk of said subject (belt is worn around the body, column 3, lines 13-16), means for processing and analyzing the position of said element (processing unit 26, column 3, lines 50-53); means for storing in the memory the phase-shift measurements made by the receivers at a given time (data storage unit 22, column 3, lines 41-42); the receivers are distributed on a belt which is able to be fixed on the trunk of the subject (antenna array belt 10, column 3, lines 10-22); the analysis and processing means (processing unit 26, column 3, line 51) include a card comprising means for analogue-to-digital conversion of the signals picked up (this is a commonly known method for manipulating or transforming data, column 2, lines 39-50) and memory means common to the three receivers and arranged on the belt (data storage unit 22); means for connecting the memory means (data storage unit 22) to the processing and analysis means (processing unit 26) and for transferring the data relating to the phase shifts

measured (Figure 2 shows clearly that the processing unit 26 is connected to the data storage unit 22).

Frisch et al. fail to show measuring the phase shift of the frequency transmitted by said transmission means relative to a reference phase, and determining by triangulation on the basis of the three phase-shift measurements the position of said element; each receiver being able to measure at a given time the phase shift of said transmission frequency relative to a reference phase; means for processing and analyzing the three phase-shift measurements made by said receivers which are able to determine, by triangulation, the position of said element.

Kimchy et al. disclose a radioactive emission detector equipped with a position tracking system. Kimchy et al. teach measuring the phase shift of the frequency transmitted by said transmission means relative to a reference phase, and determining by triangulation on the basis of the three phase-shift measurements the position of said element (paragraph [0116]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have had the position location system operate with the phase shift triangulation method, as taught by Kimchy et al., in the device of Frisch et al. Different position determination systems are well known in the art, and it would be obvious to substitute any position determination system to locate the device within the body, as they would provide a suitable equivalent. In addition, it is a well known expedient to provide baseline measurements before the procedure is carried out. Using a reference position is a well known technique for determining the position of a remote

device. In the case of monitoring an ingestible capsule, it would be obvious to use the capsule in the mouth as the reference position, as the capsule has not yet begun moving through the digestive system.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US 2004/0015075) and Iddan et al. (WO 00/22975).

Frisch et al. show a method of non-invasive exploration for assessing the digestive motility and/or transit of a human or animal subject, comprising: said subject swallowing an ingestible transmitting element which is non-digestible containing means transmitting at a given fixed frequency (source 100, column 3, line 60 through column 4 line 5); measuring, at a given time using at least three reception means (antenna elements 10a through 10z, column 3, lines 10-22) distributed around said subject's trunk (belt is worn around the body, column 3, lines 13-16); determining by triangulation (column 4, lines 35-40) the position of said element (column 4, lines 10-34); defining, according to the position of said element, a data for the assessment of the digestive motility and/or transit (sensors 110 provide the data, column 3, lines 65-67). Also, the measurements corresponding to the phase shift are stored in memory means (data storage unit 22, column 3, lines 41-42); the receiving means are placed around the abdominal belt (antenna array belt 10, column 3, lines 10-22); a series of position measurements are made which are spread over time (beacon may send out an intermittent signal or transmit at the same time as the data signal, column 3 line 67

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through column 4, line 9); a non-invasive exploration system for assessing the digestive motility and/or transit of a human or animal subject, in particular for the implementation of the method according to claim 1, characterized by: on the one hand: an ingestible transmitting element which cannot be digested by said subject containing means transmitting at a given fixed frequency (source 100, column 3, line 60 through column 4 line 5); and on the other hand: receiving means comprising at least three receivers (antenna elements 10a through 10z, column 3 lines 10-22) intended to be placed around the trunk of said subject (belt is worn around the body, column 3, lines 13-16), means for processing and analyzing the position of said element (processing unit 26, column 3, lines 50-53); means for storing in the memory the phase-shift measurements made by the receivers at a given time (data storage unit 22, column 3, lines 41-42); the receivers are distributed on a belt which is able to be fixed on the trunk of the subject (antenna array belt 10, column 3, lines 10-22); the analysis and processing means (processing unit 26, column 3, line 51) include a card comprising means for analogue-to-digital conversion of the signals picked up (this is a commonly known method for manipulating or transforming data, column 2, lines 39-50) and memory means common to the three receivers and arranged on the belt (data storage unit 22); means for connecting the memory means (data storage unit 22) to the processing and analysis means (processing unit 26) and for transferring the data relating to the phase shifts measured (Figure 2 shows clearly that the processing unit 26 is connected to the data storage unit 22).

Frisch et al. fail to show measuring the phase shift of the frequency transmitted by said transmission means relative to a reference phase, and determining by triangulation on the basis of the three phase-shift measurements the position of said element; each receiver being able to measure at a given time the phase shift of said transmission frequency relative to a reference phase; means for processing and analyzing the three phase-shift measurements made by said receivers which are able to determine, by triangulation, the position of said element; and ingesting several transmitting elements over a period of time with each element having a characteristic frequency.

Kimchy et al. disclose a radioactive emission detector equipped with a position tracking system. Kimchy et al. teach measuring the phase shift of the frequency transmitted by said transmission means relative to a reference phase, and determining by triangulation on the basis of the three phase-shift measurements the position of said element (paragraph [0116]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have had the position location system operate with the phase shift triangulation method, as taught by Kimchy et al., in the device of Frisch et al. Different position determination systems are well known in the art, and it would be obvious to substitute any position determination system to locate the device within the body, as they would provide a suitable equivalent. In addition, it is a well known expedient to provide baseline measurements before the procedure is carried out. Using a reference position is a well known technique for determining the position of a remote

device. In the case of monitoring an ingestible capsule, it would be obvious to use the capsule in the mouth as the reference position, as the capsule has not yet begun moving through the digestive system.

Iddan et al. disclose a method for delivering a device to a target location. Iddan et al. teach, that said subject ingests several transmitting elements over a period of time, each transmitting element having a characteristic frequency (page 5, lines 10-15); that it comprises several transmitting elements intended to be ingested by said subject over a period of time (page 5, lines 10-15).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have had several transmitting elements ingested by the subject over a period of time in the device of Frisch, as taught by Iddan, with the motivation that a doctor may want to take multiple readings of a patient's physiological characteristics over a period of time to determine the proper treatment, and so multiple passes of the capsule would be necessary.

Claims 12, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US 2004/0015075) as applied to claims 9, 10, and 14 above, and further in view of Refael (WO 01/50941).

Refael discloses an encapsulated medical imaging system. Refael teaches that the transmitting element comprises integrated power supply means (page 14, lines 7-9); that the transmitting element comprises induced power supply means (page 14, lines 7-

9); that the belt also comprises means for the induction of the power supply of said transmitting element (the vest 21 performs the same function as the belt in Frisch, page 16, lines 11-15).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made to have utilized these different types of powering means in the system of Frisch, as taught by Refael, with the motivation that some source of power must be applied to the capsule in order for it to function, and these are well known means of powering a transmitting capsule within a patient's body.

Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US 2004/0015075) as applied to claims 1 and 9 above, and further in view of Hogrefe et al. (US 5,415,181).

Hogrefe et al. disclose a multi-channel ingestible biomedical monitoring system. Hogrefe et al. teach that the amplitude of the transmission frequency of the transmission means is modulated as a function of the amplitude of a signal picked up by a sensor (s1 and s2 in Figure 1) included in the transmitting element, said sensor being able to pick up a signal representing a physiological characteristic (abstract); that the transmitting element comprises a sensor (s1 and s2 in Figure 1) which is able to pick up a signal representing a physiological characteristic, the amplitude of the frequency transmitted by the transmission means being able to be modulated as a function of the amplitude of the signal picked up by said sensor (abstract).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used the telemetry method taught by Hogrefe, in the device of Frisch, with the motivation that some form of transmission must take place between the capsule and the belt, and this telemetry method would provide a suitable means for transmitting a signal picked up by a sensor detecting a physiological characteristic, from within a capsule in a person's body.

Claims 8 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US 2004/0015075) as applied to claims 1 and 9 above, and further in view of Iddan et al. (WO 00/22975).

Iddan et al. disclose a method for delivering a device to a target location. Iddan et al. teach, that said subject ingests several transmitting elements over a period of time, each transmitting element having a characteristic frequency (page 5, lines 10-15); that it comprises several transmitting elements intended to be ingested by said subject over a period of time (page 5, lines 10-15).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have had several transmitting elements ingested by the subject over a period of time in the device of Frisch, as taught by Iddan, with the motivation that a doctor may want to take multiple readings of a patient's physiological characteristics over a period of time to determine the proper treatment, and so multiple passes of the capsule would be necessary.

Claims 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch et al. (US 6,904,308) in view of Kimchy et al. (US 2004/0015075) as applied to claims 2 and 9 above, and further in view of Iddan et al. (EP 0667115).

Iddan et al. disclose an in-vivo video camera system. Iddan et al. teach, that the power supply of the transmitting element is triggered at given times (capsule can be designed to only capture images when muscles are squeezing, saving battery power; a high transmission frequency (1 GHz is a high frequency, column 4, line 35).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have designed the device of Frisch so that the transmitting element only transmits at certain times, as taught by Iddan, with the motivation that this would save battery power. And also to have used a high transmission frequency, as taught by Iddan, in the device of Frisch, with the motivation that a high frequency would be suitable for transmission from a capsule inside the body to an external receiver.

Response to Arguments

Applicant's arguments filed 4/21/08 have been fully considered but they are not persuasive.

In regards to applicant's arguments that one of ordinary skill in the art would not be motivated to combine Frisch and Kimchy, examiner respectfully disagrees. Kimchy teaches that other position determination systems can be used, and position determination systems using phase shift triangulation can be used to periodically

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determine the position of the object. Position tracking systems employing ultrasound, infrared, radiofrequency, magnetic fields, or optical decoding could all be used successfully. Such techniques are old and well known in the art, and one of ordinary skill in the art could have modified Frisch to use any type of positioning system for determining the position of an object in the body.

In regards to applicant's arguments that Iddan does not disclose or suggest its utility devices having their own characteristic frequency, examiner respectfully disagrees. As each unit is transmitting, it is inherently transmitting at a given frequency. This frequency can be called a "characteristic frequency".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737